

# Enhancing Substance Abuse Treatment Services to Address Hepatitis Infection Among Intravenous Drug Users Hepatitis Test and Vaccine Tracking Form

## SUPPORTING STATEMENT

### A. Justification

#### 1. Circumstances of Information Collection

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting a reinstatement from OMB for the Minority AIDS Initiative (MAI): Enhancing Substance Abuse Treatment Services to Address Hepatitis Infection among Intravenous Drug Users, Hepatitis Test/Vaccine Tracking Form (Attachment A). The previous tracking form approved under OMB No. 0930-0300, expired on May 31, 2012. This form is needed to assist SAMHSA's continuous efforts in monitoring appropriate screening, vaccination and referral of services among selected Opioid Treatment Programs (OTPs), as well as meet MAI annual reporting requirements. In short, the requested form shall be used as a monitoring device for the appropriate use of funding and to fulfill SAMHSA's annual reporting obligations.

#### **Background:**

SAMHSA has been given authority (42 CFR Part 8) to provide administrative and clinical oversight of the nation's Opioid Treatment Programs (OTPs). Under this ruling, SAMHSA regulates the use of methadone in accredited OTPs in accordance with standards established by the Center for Substance Abuse Treatment (CSAT). The standards emphasize improving the quality of care among intravenous drug users (IDUs) by monitoring medical dosing regimens and treatment plans, improving medical supervision, assessing patient outcomes and integrating the treatment of co-occurring disorders i.e. HIV and Hepatitis C infections.

It is well known that many IDUs are Co infected with HIV and HCV. These two viruses are similar in a number of ways, and infection with both is a serious problem. Studies have shown that HIV infection in a person who is also infected with HCV results in higher levels of HCV in the blood, more rapid progression to HCV-related liver disease, and increased risk for cirrhosis and liver cancer.

Among the new cases of viral hepatitis C reported to CDC, injection-drug use is the most common risk factor. Research shows that injection-drug users (IDUs) have high rates of viral hepatitis infection with an estimated 64% chronically infected with HCV and up to 11% chronically infected with HBV. IDUs are not only disproportionately affected by these viruses, but they again are more likely to have worse adverse viral-related outcomes compared to other infected populations - primarily because of related health conditions (known as "co-morbidities") and inadequate access to and receipt of needed health services.

The Senate Labor, Health, and Human Services (LHHS) FY12 committee report noted this high incidence of hepatitis among injection drug users and urged SAMHSA to implement viral hepatitis testing as a standard of care in drug-treatment programs. The Committee also encouraged SAMHSA to implement best practice standards for infectious disease testing that includes HCV rapid testing and referral services.

In addressing the above SAMHSA established the ***Enhancing Substance Abuse Treatment to Promote Healthy Lifestyles through Addressing Hepatitis Infection among Injection Drug Users*** (contract no.283-07-5302) contract in 2010. This contract (now in third year) enhances SAMHSA ability in providing better services for appropriate screening, treatment and referral of services for IDUs at risk for HCV infection.

The funding for this contract is from the Secretary of Health MAI. The MAI is part of a cross-agency response to the existing health care disparities among intravenous drug users in the 12 U.S. jurisdictions that bear the highest AIDS burden in the country. In compliance, SAMHSA has selected 10 Opioid Treatment Programs within the 12 jurisdictions (cities/states) with high prevalence of HIV/AIDS infection as defined by MAI.

The grantees of are required to integrate efforts to prevent new viral hepatitis infections, identify hepatitis infected persons, and to provide better linkages and referrals to care and treatment. All clients who are considered to be at risk for viral hepatitis C (as specified by CDC recommendations) should be tested. All clients testing positive for viral hepatitis C should then be referred for appropriate treatment and follow-up.

The contractor is responsible for collecting completed forms from each OTP monthly. The data are then submitted to SAMHSA quarterly and annually in aggregated form. The data is designed to assist SAMHSA in accessing the program's screening activities, as well as to monitor the receipt of hepatitis tests/vaccines. The data will not be used to evaluate programs or program impacts; they will be used for administrative, service receipt purpose only

To ensure that the MAI target population is served, the selected sites each serve a minority population of at least 50%. All clients/patients shall be educated about the importance of the project and shall be given the option to participate or decline by written/signed consent.

The selected sites are located in the following cities/states:

Atlanta, GA; Cocoa, FL, Miami, FL, Orlando, FL; Sacramento, CA, San Francisco, CA and Washington DC.

SAMHSA is authorized under section 505 of the Public Health Service Act (42 USC §290aa-4) to collect data annually on the national incidence and prevalence of mental illness and substance abuse. However, under this contract in accordance to the Secretary of Health MAI funding requirements, SAMHSA is required to collect data on specific minority populations served in awarded OTPs for annual reporting. The current form seeks information relevant to such data collections.

The form collects limited patient information from those who participate in the MAI program. The information that SAMHSA requires also serves to justify the use of Federal funds to benefit these communities.

Thus, the data collected will continue to help SAMHSA in monitoring appropriate screening, vaccination and referral of services, as well as to meet its annual [minority] reporting requirements. These efforts are paramount in reducing the incidence of liver disease among Opioid Treatment programs (OTPs) high risk minority patients.

The attached tracking form collects the following: (Attachment A)

1. Risk Factors (Section A)
2. Demographics; age and ethnicity/race (Section. B)
3. Viral Hepatitis Testing /results with conformation; consent to test (Section C)
4. Services provided / vaccination, education, counseling (Section. D)
5. Type of referral services involving specialized counseling, primary care or specialty hepatitis (gastroenterology, infectious disease, psychiatry, reproductive/prenatal) care for individuals who test positive for HBV or HCV infection (Section. E)

Information System Security Plan is compliant with National Institute of Standards and technology (NIST) Special Publication (SP) 800-18, rev1. (Attachment B)

## **2. Purpose and Use of Information**

The data collected by this form will assist SAMHSA in continuous monitoring of appropriate screening, vaccination and referral of services in selected OTPs. These efforts again are paramount to reducing the incidence of liver disease among Opioid Treatment programs (OTPs) high risk minority patients.

Also in accordance to the Secretary of Health MAI funding requirements, this form will allow SAMHSA to continue to meet its annual reporting obligations as specified in the contract. The current form seeks information relevant to such data collections.

SAMHSA/CSAT Hepatitis Test and Vaccine Tracking Form is one-page, and it takes approximately 3 minutes to complete.

The form will collect limited patient information. It does contain space for lot number identification in the event that the FDA determines that problems exist with a specific lot; such problems have already occurred in several areas of the United States, making this information of critical importance to providers and to patients. The form also contains a grantee provider number for tracking purposes only.

When a client comes into the provider organization to request to be screened for hepatitis, the provider will provide a no cost hepatitis test. The corresponding Hepatitis Test and Vaccine Tracking Form will be completed by the provider. The provider will complete the form at the time the test is performed. The completed form is placed in the client's record. At the time the provider receives the results, a decision is made to continue with the vaccination series or refer the patient to follow-up services. Approximately one month after the initial intake, the forms are sent to the contractor.

Prior to implementation of this collection, SAMHSA will consult with a professional institutional review board and determine whether the collection is exempted from review, informed consent may be waived, or informed consent must be provided.

SAMHSA/CSAT will not make any generalizations or national estimates about these clients who are served or the programs serving them.

### **3. Use of Information Technology**

The design of the SAMHSA/CSAT Hepatitis Test and Vaccine Tracking Form encourages the use of automation to reduce burden on participating opioid treatment programs. The form can be completed within Microsoft Word and then e-mailed; it can be completed by hand and faxed or mailed in pre-paid envelopes. Additionally, if the program previously collects the information needed on the form, they can send the information in the format they use. The use of information technology and the methods for transmitting the form will be determined by program based on the least burden for the opioid treatment program staff.

For the programs where electronic submission increases burden, paper forms will be preprinted and provided at no cost to the opioid treatment programs as needed.

Electronic transmission of sensitive information will be FISMA compliant.

### **4. Efforts to Identify Duplication**

The information is collected only for the purposes of this program and is not available elsewhere. It is possible that the information requested by the SAMHSA/CSAT Hepatitis Test and Vaccine Tracking Form is already being collected by the participating opioid treatment programs. In the cases where the opioid treatment program has a hepatitis protocols in place, the information can be sent without reliance on the form.

### **5. Involvement of Small Entities**

The participating opioid treatment programs are usually small not-for-profit organizations, not dominant in the field. They are considered “small entities” but they do not have a significant impact on these organizations.

### **6. Consequences if Information is Collected Less Frequently**

This is a cross-sectional information collection. Providers are asked to complete one form per client screened.

If the information is not collected, the program will be contacted by phone in order to determine the problem. For those cases, when the third dose information is not received, the program will be contacted to verify that the patient did not return for the service.

### **7. Consistency with the Guidelines in 5 CFR 1320.5 (d) (2)**

This information collection fully complies with 5 CFR 1320.5 (d) (2).

**8. Consultation outside the Agency**

The notice required in 5 CFR 1320.8 (d) was published on April 23, 2012 (Vol. 77, p. 24211). No comments were received.

CSAT e-mailed the following potential respondents draft copies of the form to solicit views on whether the information requested was reasonable and whether the form was written in plain, unambiguous language.

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**9. Payment to Respondents**

Respondents will not be paid.

**10. Assurance of Confidentiality**

The information the forms are stored and compiled by a contractor which has experience in securing the information collected during the collection processing (electronically via unique secured password). The contractor recognizes the importance of restricting access to data of this nature. The information will be compiled in aggregated form only.

**11. Questions of a Sensitive Nature**

The information collection includes questions concerning sensitive information such as the patient's risk factors, and no patient identifying information is collected. The information collected relates the normal use of hepatitis vaccination and testing in the community. The opioid treatment program retains all patient identifying information and the code by which a specific patient can be identified. The Federal Government receives only a randomly assigned patient identifier which can only be used to determine that a specific unknown patient received the test kit and that certain demographic and referral information.

**12. Estimates of Project Hour Burden**

Form	Number of Screened Respondents	Responses/ Respondents	Hours/Response	Total Hour Burden	Hourly Wage Cost	Total Hour Cost
Hepatitis Test and Vaccine Tracking Form	800	1	0.05	40	\$38.15	\$1,526

**13. Estimates of Annualized Cost Burden to Respondents**

This information is routinely collected and stored. There are no system, technology acquisition, capital, or start-up costs associated with its collection.

**14. Estimates of the Annualized Cost to the Government**

The annualized cost to the government is approximately \$93,000 which will be expended to cover distribution and collection of the tracking form. This cost includes a 5 percent time commitment of Federal FTE at GS- 14 level at an estimated cost of \$5,500 annually.

**15. Changes in Burden**

This is a reinstatement of a previous approval. Previously SAMHSA/CSAT estimated that it would screen approximately 50,000 respondents with a total of 2,500 burden hours. There is decreased adjustment of 49,200 respondents/responses and 2,460 burden hours.

**16. Time Schedule, Publication, and Analysis Plans**

The aggregation of this information may be used at SAMHSA sponsored conferences, and in reports to the Secretary of Health or Congress.

**Activity and time schedule**

The information is collected on a continuous basis by the grantee. The information will be compiled by the contractor and sent to SAMHSA quarterly.

**17. Display of Expiration Date**

The expiration date for OMB approval will be displayed.

**18. Exceptions to Certification Statement**

This collection of information involves no exceptions to the Certification for Paperwork Reduction Act Submissions. The certifications are included in this submission.



**B. There are no statistical methods.**

**List of Attachments**

Attachment A: SAMHSA/CSAT Hepatitis Tracking Form

Attachment B: SAMHSA IT Clearance Plan